

C. REMARKS /ARGUMENTS

1. Status of the Claims

Claims 1-30 and 33-37 are currently pending in the application.

(Claims 31 and 32 are hereby canceled in this Amendment, as discussed in section 3 below.)

Claims 1, 24, and 35 are independent. Claims 2-23, 25-26, 33-34, and 36-37 depend on claim 1. Claims 27-30 depend on claim 24.

Claims 1, 7, 9, and 24 have been amended. No new matter is added by these amendments. Support for these amendments can be found throughout the specification, as discussed in full in section 3 below.

2. Rejection of Claims 7 and 9 under 35 U.S.C. § 112

Claims 7 and 9 stand rejected under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, it has been pointed out that there is lack of antecedent basis in claim 7 for the limitation "said optic cable" in line 2 of claim 7, and that there is lack of antecedent basis in claim 9 for the limitation "said fiber optical element," in line 3 of claim 9.

Claims 7 and 9 have been amended, in response to these rejections, to provide proper antecedent basis for these limitations (See Section B). Applicant submits that by these amendments, the rejections of Claims 7 and 9 have been overcome. activity

3. Rejection of Claims 1-18 and 24-37 35 U.S.C. § 102(e)

Claims 1-18 and 24-37 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Pat. No. 6,320,935 by Shinar et al. ("Shinar"). The Applicant respectfully traverses these rejections.

In response to the Examiner's rejections, Applicant has amended independent claims 1 and 24, and has canceled independent claims 31 and 32.

In particular, Applicant has amended independent claims 1 and 24 to recite that the photodetector is in optical communication with the scintillator by way of said optical delivery

structure. This amendment adds no new matter, and is fully supported by the specification. For example, FIG.s 2(a) and 2(b) show that light from the scintillator 118 reaches the photodetector 120 by being transmitted back through the optical delivery structure 113. FIG.s 2(a) and 2(b) show the arrows, indicating the direction of the traveling light photons, in the optical fiber 113 that come back from the scintillator 118 to the proximal end 113A of the optical fiber. As seen in FIG.s 2(a) and 2(b), the light rays or photons then go through the dichroic mirror 170 and the bandpass filter 180 to reach the photodetector 120. The specification therefore shows that the photodetector 120 is in optical communication with the scintillator by way of the optical delivery structure.

Applicant submits that Shinar does not anticipate the invention recited by amended independent claims 1, 24, and by original claim 35, which is very different from the dosimeter disclosed and described in Shinar. In the embodiment disclosed in Shinar, the photodetector is not in optical communication with the scintillator by way of the optical delivery structure (which transmits incident input light), in contrast to the requirements of amended claims 1 and 24. Nor is the photodetector in optical communication with the fiber optic cable, as required by clause E of claim 35.

In contrast, in Shinar the optical delivery structure (which is referred to in Shinar as an “optical conductor 42”) does not communicate at all with photodetector 46, i.e. does not communicate with the dosimeter unit 24 that contains the photodetector 46. (See Shinar, FIG. 1, which shows the optical conductor 42 originating from the light source and going through the insertion device 16 to reach the transducer 18.) Rather, the photodetector is in optical communication with the scintillator by way of the scintillator itself, which in Shinar is a scintillating optical fiber having a proximal end connected to the photodetector and a distal end located adjacent to or inside the miniature energy transducer. See Shinar, col. 6 line 66 – col. 7 line 3:

The proximal end of the scintillating optical fiber 26 is connected to the photo-multiplier 46, and the distal end of the scintillating optical fiber 26 is located adjacent to or inside the miniature energy transducer 18.

It is well established that a prior art reference anticipates a claim only if the reference

discloses all the elements and limitations of the claim. If even one element or limitation of the claim is missing, a § 102 rejection fails. See e.g. Kalman v. Kimberly-Clark, 713 F.2d 760, 771, 218 U.S.P.Q. 781 (Fed. Cir. 1983).

Applicant respectfully submits that Shinar does not anticipate the invention as recited in the amended independent claims 1 and 24, and in original independent claim 35, because Shinar does not teach or suggest at least the following limitations of independent claims 1, 24, and 35, because of the reasons set forth above:

“a photodetector in optical communication with said scintillator by way of said optical delivery structure” (amended independent claims 1 and 24); and

“a photodetector in optical communication with said fiber optic cable” (claim 35).

Applicant submits that claims 1, 24, and 35 therefore are allowable, and not anticipated by Shinar.

Claims 2-18, 25-26, 33-34, and 36-37 all depend on claim 1, and therefore include all the limitations of claim 1. Claims 2-18, 25-26, 33-34, and 36-37 are therefore allowable at least because they depend from an allowable base claim. Claims 27-30 depend on claim 24, and therefore include all the limitations of claim 24. Claims 27-30 are therefore allowable at least because they depend from an allowable base claim.

For these reasons, Applicant submits that claims 1-18, 24-30, and 33-37 are allowable, and not anticipated under 35 U.S.C. § 102 (e) by Shinar. Applicant respectfully requests that the rejection of claims 1-18, 24-30, and 33-37 under 35 U.S.C. § 102(e) as being anticipated by Shinar be withdrawn.

4. Rejection of Claims 19-23, 27-30, and 37 under 35 U.S.C. 103(a)

Claims 19-23, 27-30, and 37 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Shinar. Applicant respectfully traverses these rejections.

Applicant submits that claims 19-23, 27-30, and 37 are allowable as depending on an allowable base claim (amended claim 1).

In addition, Applicant respectfully traverses the Examiner’s additional arguments for rejecting claims 19-23, 27-30, and 37, as follows:

Claims 19-21

Regarding claims 19-21, the Examiner states:

With respect to claims 19-21 Shinar teaches that scintillator can be made from any appropriate material with many modification and variations (column 10; lines 38-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the scintillator made from: a crystalline material; or material selected from the group consisting of sodium-iodide, cesium-iodide, bismuth-germinate, cesiumfluoride, ZnS, YAP:Ce (yttrium aluminum perovskite), terbium doped glass fiber, or material selected from the group consisting of glass, terbium doped glass fiber, and polymers, since it has been held that to be within the general skill of a worker in the art to select a known material on the bases its suitability for the intended use. In re Leshin, 125 USPQ 416

As an initial matter, Applicant notes that Column 10, lines 38-45 of Shinar read as follows:

The invention has been described with reference to certain preferred embodiments thereof. It will be understood, however, that modification and variations are possible within the scope of the appended claims. For example, other types of optical scintillating fibers may be utilized, and other signal processing devices may be incorporated into the post processor to process the output from the photomultiplier.

As seen from the above-quoted portion of Shinar, there is no mention or suggestion that the scintillator “can be made from any appropriate material.” Rather, Shinar merely states that “other types of optical scintillating fibers may be utilized.”

Applicant submits that Shinar fails to suggest the desirability of modifying the apparatus disclosed in Shinar to incorporate the limitations of claims 19-21 above. In particular, there is no teaching or suggestion in Shinar that the materials recited in claims 19-21 (“crystalline material” in claim 19; “sodium-iodide, cesium-iodide, bismuth-germinate, cesiumfluoride, ZnS, yttrium aluminum perovskite, terbium doped glass fiber” in claim 20; and “glass, terbium doped glass fiber, and polymers” in claim 21) could be used as a scintillator in the miniaturized sizes and scales that are disclosed in the present application and in Shinar as being typical of x-ray brachytherapy systems. See Shinar column 6, lines 23-24 (“The diameter of the optical fiber 26 preferably ranges from 0.01 mm to 1 mm.”); Shinar column 7, lines 21-23 (“The electrically insulating tube 56 is sealed and it is preferably 3-9 mm in length and less than 1.7 mm in

diameter . . . “); Applicant’s specification page 13, lines 5-7 (“In an exemplary embodiment, the fiber optic cable 113 may have a diameter of about 200 microns, and the flexible metallic sheath 105 may have a diameter of about 1.4 mm . . . “); Applicant’s specification page 13, lines 21-22 (“The radiation generator assembly 101, which in one embodiment may be about 0.5 cm to about 2 cm in length . . . “).

It is well established that, in rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Also, “[t]he mere fact that the prior art *may* be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” In re Fritch, 972 F.2d 1260, 1266, 12 USPQ2d 1780, 1783-84 (Fed. Cir. 1992).

Applicant submits that the Examiner’s rejection of claims 19-21 under 35 U.S.C. 103 does not establish a *prima facie* case of obviousness, because: 1) Shinar does not teach or suggest the above-discussed limitations in claims 19-21 relating to constituent materials for optical fibers; and 2) Shinar fails to suggest in any way the desirability of modifying the scintillator fiber in Shinar to include the materials disclosed in claims 19-21. Therefore, claims 19-21 are not rendered obvious by Shinar.

Claims 22, 23, and 27-30

Regarding claims 22, 23, and 27-30, the Examiner states:

With respect to claims 22,23 and 27-30 Shinar teaches that the electron source can comprise any appropriate configurations and materials with many modification and variations (column 3; lines 40-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the electron source includes a photocathode having a photosensitive surface and having a thermionic cathode having an electron-emissive surface and adapted to emit electrons since it has been held that to be within the general skill of a worker in the art to select a known material on the bases its suitability for the intended use. In re Leshin, 125 USPQ 416.

Applicant respectfully traverses.

Applicant submits that Shinar fails to teach or suggest all the limitations of claims 22, 23,

and 27-30, namely a therapeutic radiation source having: 1) an in-situ radiation detecting system, including a scintillator for generating light in response to therapeutic radiation incident thereon; 2) a photodetector in optical communication with the scintillator by way of an optical delivery structure; and 3) a laser-heated thermionic cathode (claim 22), a photocathode (claim 23), a thermionic cathode made of metal (claim 27), the metal for the thermionic cathode including tungsten, thorated tungsten, tungsten alloys, and tantalum (claim 28), the thermionic cathode including a metallic base coated with an oxide (claim 29), and the oxide including barium oxide, strontium oxide, and calcium oxide, and the metallic base including nickel (claim 30).

Applicant further submits that Shinar fails to teach or suggest in any way the desirability of modifying the apparatus disclosed in Shinar to include the limitations set forth in the previous paragraph. Applicant submits that therefore the Examiner's rejection of claims 22, 23, and 27-30 (which depend on amended claim 1) under 35 U.S.C. 103 does not establish a *prima facie* case of obviousness, and that claims 22, 23, and 27-30 are not rendered obvious by Shinar.

Claim 37

Regarding claim 37, the Examiner states:

With respect to claim 37, Shinar fails to disclose LED (light emitting diode) as an optical source. Since LED is well known light source in the X-ray art, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide LED as an alternative light source for the therapeutic apparatus of Shinar

Applicant respectfully traverses.

Applicant submits that Shinar fails to teach or suggest all the limitations of claim 37, namely a therapeutic radiation source having an in-situ radiation detecting system, and including: 1) an LED for generating light directed to an optical delivery structure that transmits the light onto a radiation generator assembly; 2) a scintillator for generating light in response to therapeutic radiation incident thereon; and 3) a photodetector in optical communication with the scintillator by way of the optical delivery structure.

Applicant further submits that Shinar fails to teach or suggest in any way the desirability of modifying the apparatus disclosed in Shinar to include the limitations set forth in the previous paragraph. Applicant submits that therefore the Examiner's rejection of claim 37 under 35 U.S.C. 103 does not establish a *prima facie* case of obviousness, and that claim 37 is not

rendered obvious by Shinar.

For these reasons, Applicant respectfully submits that claims 19-23, 27-30, and 37 are not rendered obvious under 35 U.S.C. 103(a) by Shinar, and that claims 19-23, 27-30, and 37 are allowable.

5. Rejection of Claim 5 Under 35 U.S.C. 103(a)

Claim 35 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Shinar in view of US Pat. No. 5,606,163 to Huston et al. ("Huston"). Applicant respectfully traverses.

Applicant submits that Shinar and Huston, either alone or in combination, fail to teach or suggest the subject matter of claim 35, namely 1) a scintillating optical fiber which a) transmits incoming light onto an therapeutic radiation source that generates therapeutic radiation in response to the incoming light, and b) is disposed along a path of the therapeutic radiation so as to generate scintillator light in response to incident therapeutic radiation; and 2) a photodetector in optical communication with the scintillator.

Nowhere in the cited references (Shinar and Huston) is there any suggestion, teaching, or motivation to combine the references on which the rejection is based. A *prima facie* case of obviousness cannot be established, absent any suggestion, teaching, or motivation to combine. The subject matter of Huston is thermoluminescence (i.e. light emission that results when substances that have been irradiated are heated), and has nothing to do with optically activated x-ray brachytherapy systems, as described in the present application. In particular, the optical fiber 27 in Huston is not made of scintillating material and does not generate scintillator light in response to incident therapeutic radiation, in contrast to the requirements of claim 35. Nowhere in Hudson is there any disclosure of any optical fiber that directs light onto an electron source so as to cause the emission of electrons, which in turn strike a radiation target to generate therapeutic radiation. (In Hudson, the dosimeter includes pre-irradiated thermoluminescent material.)

Moreover, even if the references were so combined, the combination of Shinar and Huston would in any case fail to teach all of the elements and limitations recited in claim 35,

because neither reference teaches or suggests the any scintillating optical fiber that both 1) transmits light onto a therapeutic radiation generator so as to cause emission of therapeutic radiation, and 2) generates scintillator light in response to incident therapeutic radiation.

For these reasons, it is submitted that there is no proper basis for the 35 U.S.C. § 103 rejection of claim 35, which is not rendered obvious by Shinar and Huston. Applicant respectfully submits that claim 35 is allowable.

6. **Conclusion**

On the basis of the foregoing amendments, Applicant respectfully submits that all of the pending claims 1-30 and 33-37 are in condition for allowance. An early and favorable action is therefore earnestly solicited. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Elizabeth E. Kim

Elizabeth E. Kim, Reg. No. 43,334
McDermott, Will & Emery
28 State Street
Boston, MA 02109
(617) 535-4411
(617) 535-3800

Date: February 13, 2004